

PHARMACY BOARD[657]

Amended Notice of Intended Action

Proposing rule making related to USP general chapter 800 and providing an opportunity for public comment

The Board of Pharmacy hereby proposes to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76, 155A.2 and 155A.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.2 and 155A.13.

Purpose and Summary

The United States Pharmacopeial Convention establishes national minimum standards for a number of health care related topics. United States Pharmacopeia (USP) General Chapter 800, enforceable by the federal Food and Drug Administration, provides the national minimum standard for the proper handling of hazardous drugs to protect health care workers, patients, and the environment and will become effective (enforceable) December 1, 2019. In advance of the effective date of USP General Chapter 800, this proposed amendment requires all pharmacies to ensure adequate protection of pharmacy personnel and patients from hazardous drugs and provides an official enforcement date for Iowa pharmacies to implement the standards identified in USP General Chapter 800.

Reason for Amendment of Notice of Intended Action

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 29, 2018, as **ARC 3978C**. The Board received two comments requesting clarification on the expected enforcement date in Iowa for standards identified in USP General Chapter 800. The proposed amendment has been changed to instead provide a date upon which the Board intends to enforce the standards of USP General Chapter 800, which is set for December 1, 2019, or later if so delayed by USP. The revision is substantial enough to warrant a second period for public comment.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs is anticipated or can be determined. It is unknown to what extent each individual pharmacy will need to implement protective measures to protect its personnel who handle hazardous drugs.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on January 8, 2019. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309
Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend rule 657—8.5(155A) as follows:

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment shall be available in an amount and type to provide secure, environmentally controlled storage of drugs ~~shall be available~~.

8.5(1) to 8.5(10) No change.

8.5(11) Hazardous drugs. The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, or the enforcement date identified by the United States Pharmacopeia (USP), whichever is later, the pharmacy shall be in compliance with USP General Chapter 800 for handling hazardous drugs.